

AMENDMENTS TO THE DRAWINGS:

Please add new Fig. 5 to this application. Fig. 5 depicts a device with a plurality of indicators. The originally-filed specification, drawings, and claims fully support the subject matter of Fig. 5. No new matter has been introduced.

Attachments: One (1) drawing marked NEW SHEET including Fig. 5.

REMARKS

Applicant submits this Amendment in reply to the Office Action mailed May 4, 2006.

By this Amendment After Final, Applicant adds new Fig. 5, amends the specification, cancels claims 6, 17, 25, 40-42, 44, and 54, and amends claims 1, 16, 24, 43, and 52. The originally-filed specification, drawings, and claims fully support the subject matter of new Fig. 5, the amended specification, and amended claims 1, 16, 24, 43, and 52. No new matter has been introduced.

Claims 1-5, 7-10, 12-16, 18-24, 26-29, 31-39, 43, 45-53, and 55-60 are now in this application. Claims 1, 16, 24, 43, and 52 are the sole independent claims.

On page 2 of the Office Action, the drawings were objected to. Applicant submits herewith new Fig. 5 depicting a device with a plurality of indicators, and also amends the specification to reference new Fig. 5. Accordingly, Applicant respectfully requests withdrawal of the drawing objection.

On pages 3-7 of the Office Action, claims 1-10, 12-29, and 31-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,518,927 to Malchesky et al. ("Malchesky"). Applicant has incorporated the subject matter of dependent claims 40-42 into independent claims 1, 16, and 24, respectively. Claims 40-42 were not rejected over Malchesky. Accordingly, this rejection is now moot, and Applicant respectfully requests withdrawal of the Section 102(b) rejection based on Malchesky.

On pages 8-11 of the Office Action, claims 1, 16, 24, 37-47, and 49-60 were rejected under 35 U.S.C. §§ 102(b)/103(a) as being unpatentable over U.S. Patent

Application Publication No. 2002/011931 A1 to Quattrocchi et al. ("Quattrocchi").

Applicant respectfully traverses this rejection.

Quattrocchi does not disclose or suggest the claimed invention. For example, independent claim 1 recites "an indicator printed directly on the medical device." Independent claims 16, 24, 43, and 52 recite similar aspects. Quattrocchi does not disclose at least these aspects of each of independent claims 1, 16, 24, 43, and 52 either alone or in combination with the other aspects of each of independent claims 1, 16, 24, 43, and 52.

Quattrocchi discloses a testing apparatus 20 in which a specimen of blood, urine, or other fluid or specimen is placed on portion 24. The specimen then flows into an interior of housing 21, reacts with indicators 27, 28, 29, and any color change in indicators 27, 28, 29 is visible in display portion 25. None of indicators 27, 28, 29, nor any chemical included in indicators 27, 28, 29, however, is printed directly on testing apparatus 20 as set forth in the claimed invention. Indeed, in rejecting dependent claim 44, page 10 of the Office Action asserts that "printing would have been an obvious means to one of ordinary skill in the art for applying the indicator to the testing strip," essentially admitting that Quattrocchi does not disclose "printing the indicator directly on the medical device." Insofar as the Office Action is asserting that such a modification would have been obvious, however, Applicant respectfully disagrees.

As an initial matter, page 8 of the Office Action cites page 2, paragraph 21, and Fig. 2 of Quattrocchi as referring to indicators 27, 28, 29 that allegedly correspond to the indicator of the claimed invention. While lines 19-23 of that paragraph of Quattrocchi do disclose that the "indicators" may be provided in the form of a film sticker, Applicant

believes that this is a typographical error, as film sticker 33 in Fig. 2 includes identifiers 30, 31, 32, and not indicators 27, 28, 29. Indeed, the referenced portion of the Quattrocchi specification further discloses that "it is possible for numerous identical specimen testers to be manufactured, and these provided with various different stickers that contain different *identifiers*, or that contain the same *identifiers* in a different order." (Emphasis added). The indicators 27, 28, 29, on the other hand, are provided with housing 21, in communication with portion 24 to receive the fluid specimen, and underneath sticker 33.

Additionally, even if indicators 27, 28, 29 were on sticker 33 (which they are not), page 3, lines 3-10 of the originally-filed specification specifically disparages the use of stickers as indicators as follows:

Another way to determine that a medical device is sterile is through the placement of labels, stickers, or tapes on the medical device or packaging. The labels, stickers, or tapes may contain chemicals that change color, for example, when exposed to a nonsterile or other undesirable environment, an undesirable temperature, or a potentially hazardous chemical for any duration. However, labels, stickers, or tapes placed on the device packaging presents the same problems discussed above. In addition, labels, stickers, or tapes can be removed and/or fall off when placed on the medical device itself.

As independent claim 1 now recites, "an indicator printed directly on the medical device," and independent claims 16, 24, 43, and 52 recite similar aspects, it is clear that a sticker would not anticipate an indicator according to the claimed invention.

In any case, however, it would not have been obvious to modify the Quattrocchi device to print indicators 27, 28, 29 directly on testing apparatus 20. Indeed, if indicators 27, 28, 29 were printed directly on testing apparatus 20, it would either be (1) on the outside of housing 21, inhibiting or preventing its contact with the specimen that

was placed on portion 24, which flows internally through housing 21, or (2) on the inside of housing 21 and thus either not be visible at all or difficult to view. In the first scenario, if indicators 27, 28, 29 were printed directly on housing 21 and could not contact the specimen on the inside of housing 21, then they could not change color, rendering testing apparatus 20 of Quattrocchi unsatisfactory for its intended purpose, In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), and impermissibly changing the principle of operation of Quattrocchi, In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The same is true for the second scenario, where if indicators 27, 28, 29 are not visible because they are printed on the inside housing 21, testing apparatus 20 would be useless, also rendering Quattrocchi unsatisfactory for its intended purpose, and impermissibly changing the principle of operation of Quattrocchi.

Accordingly, for at least these reasons, Applicant respectfully requests withdrawal of the Section 102(b) rejections based on Quattrocchi.

Claims 2-5, 7-10, 12-15, 18-23, 26-29, 31-39, 45-51, 53, and 55-60 depend from one of independent claims 1, 16, 24, 43, and 52, and are therefore allowable for at least the same reasons that each of the corresponding independent claims is allowable. In addition, each of the dependent claims recite unique combinations that are neither taught nor suggested by Malchesky, Quattrocchi, and Pronovost and therefore are separately patentable.

In view of the foregoing remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to these or any other statement or characterization in the Office Action.


In discussing the specification and claims in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please enter any extension of time necessary to submit this Amendment, and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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